



IFW

Atty. Dkt. No. 047630-0201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Ma, et al.

Title: ANTIBODIES SPECIFIC FOR  
CANCER ASSOCIATED  
ANTIGEN SM5-1 AND USES  
THEREOF

Appl. No.: 10/722,849

Filing Date: 11/26/2003

Examiner: Unknown

Art Unit: 1614

<p><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>Marisol Moretto</u> (Printed Name)</p> <p><u><i>Marisol Moretto</i></u> (Signature)</p> <p><u>April 28, 2006</u> (Date of Deposit)</p>
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**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment -IDS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

Respectfully submitted,

Date 04/27/2006

By Barry S. Wilson

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Barry S. Wilson  
Attorney for Applicant  
Registration No. 39,431

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<p>Substitute for form 1449B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>Date Submitted: April 27, 2006</p> <p>(use as many sheets as necessary)</p> <p>1 of 8</p>	<p style="text-align: center;"><b>Complete if Known</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td>10/722,849</td> </tr> <tr> <td>Filing Date</td> <td>11/26/2003</td> </tr> <tr> <td>First Named Inventor</td> <td>MA</td> </tr> <tr> <td>Group Art Unit</td> <td>1614</td> </tr> <tr> <td>Examiner Name</td> <td>Unknown</td> </tr> <tr> <td>Attorney Docket Number</td> <td>047630-0201</td> </tr> </table>	Application Number	10/722,849	Filing Date	11/26/2003	First Named Inventor	MA	Group Art Unit	1614	Examiner Name	Unknown	Attorney Docket Number	047630-0201
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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	B1	6,214,318		Benz et al.	04/2001	
	B2	RE 32,417		Burchiel et al.	05/1987	
	B3	4,036,945		Haber	07/1977	
	B4	4,311,688		Burchiel et al.	01/1982	
	B5	4,472,371		Burchiel et al.	09/1984	
	B6	4,478,815		Burchiel et al.	10/1984	
	B7	4,478,818		Shell et al.	10/1984	
	B8	5,223,409		Ladner et al.	06/1993	
	B9	5,317,091		Subramanian	05/1994	
	B10	5,475,096		Gold et al.	12/1995	
	B11	5,530,101		Queen et al.	06/1996	
	B12	5,595,877		Gold et al.	01/1997	
	B13	5,660,985		Pieken, et al.	08/1997	
	B14	5,693,762		Queen et al.	12/1997	

**U.S. PATENT APPLICATION DOCUMENTS**

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**FOREIGN PATENT DOCUMENTS**

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B15		WO 97/47271			12/1997		
	B16		WO 98/04282			02/1998		
	B17		WO 98/16238			04/1998		
	B18		WO 98/24884			06/1988		

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NON PATENT LITERATURE DOCUMENTS			
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	B19	Aamdal et al. "Immunomagnetic Detection of Melanoma Cells in bone Marrow and Blood" Melanoma Research 7 (Suppl. 1):S35 (1997)	
	B20	Adema et al. "Molecular Characterization of the Melanocyte Lineage-Specific Antigen gp100" J. Invest. Dermatol. 104:269-276 (1994)	
	B21	Argenyi et al. "S100 Protein-negative Malignant melanoma: Fact or Fiction? A light-Microscopic and Immuno-Histochemical Study" Am. J. Dermatopathol. 16:233-240 (1994)	
	B22	Brooks et al. J. "Subtractive Immunization Yields Monoclonal Antibodies that specifically Inhibit Metastasis" Cell Biol. 122(6):1351-1359 (1993)	
	B23	Chen et al. "A Melanoma Associated Fibronectin Variant Characterized by Monoclonal Antibody SM5-1" Journal of Molecular Medicine 76: page B11 (1998)	
	B24	Cochran et al. "Detection of S100 Protein as an Aid to the Identification of Melanocytic Tumors" Int. J. Cancer 30: 295-297 (1982)	
	B25	Cohen et al. "Production and Characterisation of an Antimelanoma Monoclonal Antibody KBA.62 Using a New Melanoma Cell Line Reactive on paraffin Wax Embedded Sections" J.Clin. Pathol. 48:826-831 (1995)	
	B26	Colombiari et al. "Distribution of Melanoma Specific Antibody (Hmb-45) in Benign and Malignant Melanocytic Tumors" Virchows Archiv. A Pathol Anat. 413:17-24 (1988)	
	B27	Drier et al. "S100 Protein Immunoreactivity in Poorly Differentiated Carcinomas. Immuno-Histochemical Comparison with Malignant Melanoma" Arch. Pathol. Lab. Med. 111:447-452 (1987)	
	B28	Emery and Harris. "Strategies for Humanizing Antibodies" Chapter 6 In <u>Antibody Engineering</u> 2 <sup>nd</sup> Ed. Pp. 159-183 (1995)	
	B29	Esclamado et al. "Unique Proteins Defined by Monoclonal Antibodies Specific for Human Melanoma. Some Potential Clinical Applications" Am. J. Surg. 152:376-385 (1986)	
	B30	Frye et al. "Detection of Amplified Oncogenes by Differential Polymerase Chain Reaction" Oncogene 4:1153-1157 (1987)	

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	B31	Gatter et al. "An Immunocytochemical Study of Malignant melanoma and its Differential Diagnosis from Other Malignant Tumors" J. Clin. Pathol. 38:1353-1357 (1985)	
	B32	Giorno. "A Comparison of Two Immunoperoxidase Staining Methods Based on the Avidin-Biotin Interaction" Diag. Immunol. 2:161-166 (1984)	
	B33	Gown et al. "Monoclonal Antibodies Specific for Melanocytic Tumors Distinguished Subpopulations of Melanocytes" Am. J. Pathol. 123:195-203 (1986)	
	B34	Guo et al. "Inhibition of Human melanoma Growth and Metastasis In Vivo by Anti-CD44 Monoclonal Antibody" Cancer Res. 54:1561-1565 (1994)	
	B35	Hachisuka et al. "Immuno-Histochemical Study of S100 Protein and Neuron Specific Enolase (NSE) in Melanocytes and the Related Tumors" Acta Histochem. 80:215-223 (1986)	
	B36	Hannum et al. "Ligand for FLT/3/FLK2 receptor tyrosine kinase regulates growth of haematopoietic stem cells and is encoded by variant RNAs" Letters to Nature 368: 643-648 (1994)	
	B37	Harlow and Lane. Chapter 12 <i>In Antibodies-A Laboratory Manual</i> cold Spring Harbor Laboratory pp. 471-510 (1988)	

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	B38	Harlow and Lane. Chapter 14 <i>In Antibodies-A Laboratory Manual</i> Cold Spring Harbor Laboratory pp. 553-612 (1988)		
	B39	Harlow and Lane. "Immunoaffinity Purification" Chapter 13 <i>In Antibodies-A Laboratory Manual</i> Cold Spring Harbor Laboratory pp. 511-552 (1988)		
	B40	Herrera and Hancock. "Specificity of Antibody HMB-45" Arch. Pathol. La. Med. 116:900-901 (1992)		
	B41	Hung et al. "Enhancement of DNA Vaccine Potency by Linkage of Antigen Gene to a Gene Encoding the Extracellular Domain of Fms-like Tyrosine Kinase 3-Ligand" Cancer Research 61: 1080-1088 (2001)		
	B42	International Search Report for PCT Application No. PCT/US2004/040870		
	B43	Köhler et al. "Derivation of Specific Antibody Producing Tissue Culture and Tumor Lines by Cell Fusion" Eur. J. Immunol. 6:511-519 (1976)		
	B44	Mackie et al. "Use of NK1 C3 Monoclonal Antibody in the Assessment of Benign and Malignant Melanocytic Lesions" J. Clin. Pathol. 37:367-372 (1984)		

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	B45	McCarthy et al. "Localization and Chemical Synthesis of Fibronectin Peptides with Melanoma Adhesion and Heparin Binding Activities" Biochemistry 27:1380-1388 (1988)		
	B46	Mottolese et al. "Immunocytochemical diagnosis of Amelanotic Metastatic Melanoma Using Monoclonal Antibodies HMB-45 and Epl-3" Melanoma Res. 4:53-58 (1994)		
	B47	Palazo and Duray. "Typical, Dysplastic, Congenital, and Spitz nevi: A Comparative Immuno-Histochemical Study" Hum. Pathol. 20:341-346 (1989)		
	B48	Reinke et al. "Differential Expression of MART-1, Tyrosinase, and SM5-1 in Primary and Metastatic Melanoma" Am. J. Dermatopathol. 27: 401-406 (2005)		
	B49	Rothman et al. "Structure and Expression of Germ Line Immunoglobulin Heavy-Chain $\epsilon$ Transcripts: Interleukin-4 Plus Lipopolysaccharide-Directed Switching to $\text{Ce}$ " Molecular and Cellular Biology 10(4):1672-1679 (1990)		
	B50	Sekiguchi et al. Seikagaku, 1989,61, pp. 89-93 (abstract)		
	B51	Serafini et al. "Technetium-99m Labeled Monoclonal Antibodies in the Detection of Metastatic Melanoma" Clinical Nuclear Medicine 14(8):580-587 (1989)		

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	B52	Shi et al. "Antigen Retrieval in Formalin-Fixed, Paraffin-Embedded Tissues: An Enhancement Method for Immuno-Histochemical Staining Based on Microwave Oven Heating of Tissue Sections" J. Histochem Cytochem. 39:741-748 (1991)		
	B53	Smith et al. "The Human Homologue of Rat NG2, a Chondroitin Sulfate Proteoglycan, Is Not Expressed on the Cell Surface of Normal Hematopoietic Cells But Is Expressed by Acute Myeloid Leukemia Blasts From Poor-Prognosis Patients with Abnormalities of Chromosome Band 11q23" The American Society of Hematology, Blood, 87(3):1123-1133 (1996)		
	B54	Springall et al. "The Value of S100 Immunostaining as a Diagnostic Tool in Human Malignant Melanomas. A Comparative Study Using S100 and Neuron-Specific Enolase Antibodies" Virchows Arch. Pathol. Anat. Histopathol. 400:331-343 (1983)		
	B55	Stefansson et al. "Distribution of S100 Protein Outside the Central Nervous System" Brain Res. 234:309-317 (1982)		
	B56	Stefansson et al. "S100 Protein in Human Chondrocytes" nature 295:63-64 (1982)		
	B57	Sun et al. "Antibody HMB-45 Identifies the Cells of Blue Nev. An Immuno-Histochemical Study on Paraffin Sections" Am. J. Surg. Pathol. 14:748-751 (1990)		
	B58	Swerdlow et al. "Risks of Second Primary malignancy in Patients with Cutaneous and Ocular Melanoma in Denmark, 1943-1989" Int. J. Cancer 61:773-779 (1995)		

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	B59	Tabuchi et al. "A S100 Protein in Human Glial tumors. Qualitative and quantitative Studies" Aca Neurochir. Wien 65:239-251 (1982)	
	B60	Trefzer et al. "SM5-1: a new monoclonal antibody which is highly sensitive and specific for melanocytic lesions" Arch. Dermatol. Res. 292:583-589 (2000)	
	B61	Trefzer et al. "SM5-1: A New Monoclonal Antibody Which is Highly Sensitive and Specific for Melanocytic Tumors" Journal of Dermatological Science 16 (Suppl. 1):S110 (1998)	
	B62	Trefzer et al. "The monoclonal antibody SM5-1 recognizes a fibronectin variant which is widely expressed in melanoma" BMC Cancer 6(8):1-12 (2006)	
	B63	Vanstapel et al. "New Sites of Human S100 Immunoreactivity Detected with Monoclonal Antibodies" Am. J. Clin. Pathol. 85:160-168 (1986)	
	B64	Vennegoor et al. "Biochemical Characterization and Cellular Localization of a Formalin-Resistant Melanoma-Associated Antigen Reacting with Monoclonal Antibody NKI/C-3" Int. J. Cancer 35:287-295 (1985)	
	B65	Williams et al "Subtractive Immunization Techniques for the Production of Monoclonal Antibodies to Rare Antigens" Biotechniques 12:842-847 (1992)	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/722,849
				<b>Filing Date</b>	11/26/2003
				<b>First Named Inventor</b>	MA
				<b>Group Art Unit</b>	1614
				<b>Examiner Name</b>	Unknown
Date Submitted: April 27, 2006				<b>Attorney Docket Number</b>	047630-0201
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	B66	Wilson et al. "Sulfation and Molecular Weight of Fibronectin Shed by Human Melanoma Cells" Biochem Biophys Research Commun. 101:1047-1051 (1981)	
	B67	Wu et al. "Induction of Potent TRAIL-Mediated Tumoricidal Activity by hFLEX/Furin/TRAIL Recombinant DNA Construct" Molecular Therapy 9 (5) :674-681 (2004)	
	B68	Wu et al. "Regression of Human Mammary Adenocarcinoma by Systemic Administration of a Recombinant Gene Encoding the hFlex-TRAIL Fusion Protein" Molecular Therapy 3:368-374 (2001)	

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